

Medicinal maggots cross border at a crawl

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Maggot therapy is becoming an increasingly popular choice for treating nonhealing wounds, but Canadian wound clinicians are having difficulty getting their hands on maggots. Larvae of the green bottle fly have been shown to be effective in removing dead tissue from wounds, a process called debridement. Some wound-care experts say these maggots, which leave healthy tissue alone, also consume bacteria and promote healing (*Wound Rep Reg* 2002; 10:208-14).

"I've been using maggots for six or seven years," says Christine Pearson, a wound clinician in British Columbia. "It's been very popular in the rest of the world for 10 or 15 years. Canada is one of the most backward places for maggot use — because of Health Canada."

Prior to this year, Pearson received maggots from the United States within 24 hours of ordering them. Monarch Labs, based in Irvine, California, is the primary supplier of maggots for wound care. But when Pearson applied to Health Canada in January, 2009, for a permit to import maggots, she discovered the process had become more complicated.

Health Canada had classified the maggots as drugs. Now they could only be imported through the Special Access Programme, which "provides access to nonmarketed drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable," according to the Health Canada's website (www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index-eng.php).

"Maggots are classed as drugs because their mode of action is closest to the definition of a drug, particularly a biological drug. They meet the requirements for being considered biological drugs because they originate from a biological source and do not meet the requirement for being a device, which is



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Canadian wound clinicians are finding it difficult to obtain maggots for larval therapy.

defined as an article," Christelle Legault, a media relations officer with Health Canada, wrote in an email.

"The effect of the definition is that any manufacturer must file a New Drug Submission with information on the quality, safety and efficacy of the maggots for the uses and under the conditions of use recommended. Health Canada has started to work on guidelines to address the regulatory requirements."

Health Canada had previously labelled medicinal maggots as medical devices, says Pearson. In the United States, where the Food and Drug Administration endorsed maggots for wound care in 2004, maggots are still considered prescription-only medical devices, according to Monarch Labs' website (www.monarchlabs.com).

Because of the new Health Canada classification, it now takes Canadian clinicians up to three weeks to get maggots from California. The paperwork and added hassle have prompted some people to abandon maggot therapy, says Pearson, a registered nurse and board member of the Canadian Association of Wound Care. "It's just too onerous, and it's less cost-effective when it takes so long to get them."

Pearson says Canadian parties have also applied to Health Canada for permission to manufacture and sell maggots for wound care. The University of British Columbia in Vancouver had offered space, she says, and Monarch Labs was willing to supply start-up stock. But Health Canada did not grant permission.

"Health Canada has had several enquiries on the manufacture and sale of maggots. Anyone wishing to sell maggots cannot do so without having a market authorization, which is the case with any other drug product in Canada," Legault wrote.

"Those wishing to use maggots as a form of treatment can also do this via Clinical Trials. While there are no requirements in Canada to undertake Canadian studies before a submission

can be filed, it is important to note that studies, international or domestic, will need to be conducted supporting the safety and efficacy for the marketing of a product for treatment purposes."

Though advocates for maggot therapy say research shows it can save 40%–50% of limbs with nonhealing wounds that would have otherwise been amputated, other wound care experts note that only two clinical trials on the treatment have been published.

One found that maggots were more effective than standard treatment, hydrogel, in debriding wounds (*J Tissue Viability* 2000;10:91–4). The other concluded that, while superior for debridement, maggot therapy was no better than hydrogel at increasing healing rates or decreasing bacteria (*BMJ* 2009;338:b773). — Roger Collier, *CMAJ*

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